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FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,928	MEINKE ET AL.	
	Examiner	Art Unit	
	GINNY PORTNER	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-60* is/are pending in the application.

4a) Of the above claim(s) *47,48 and 55-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-46 and 49-54* is/are rejected.

7)☒ Claim(s) *38-46 and 49-54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/18/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence alignments*.

DETAILED ACTION

Claims 1-37 have been canceled; claims 38-60 are pending.

Election/Restrictions

1. Applicant's election without traverse of Group I, species SEQ ID NO 288 encoded by SEQ ID NO 110 in the reply filed on December 13, 2008 is acknowledged; Claims 38-46, 49-54 are under consideration.

2. Claims 47-48 and 55-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, inventions , there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 13, 2008. Claims 47-48 stand withdrawn from consideration in light of Applicant electing a single polypeptide species, rather than compositions that comprise two or more polypeptides.

3. Group I, claim(s) 38-54, drawn to a plurality of species of antigen, or antigen fragments, or combination compositions of two or more antigens or fragments.

4. Group II, claim(s) 55-60, drawn to a plurality of methods of vaccinating a subject with a single antigen, or an antigen fragment or combination compositions that comprise two or more antigens or fragments.

Information Disclosure Statement

5. The information disclosure statement filed January 18, 2007 has been considered.

Priority

6. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Claim Objections

7. Claims 38-46 and 49-54 objected to because of the following informalities:

8. Claims 38-46 and 49-54 recite the indefinite article "an amino acid sequence"; this should be ----the amino acid sequence----.

9. Claims 38-46 and 49-54 are objected to for reciting a plurality of unelected inventions. .

Appropriate correction is required.

10. Claim 39 is objected to for reciting claim limitations directed to Tables 1 & 3; the claims should recite SEQ ID NOs.

2173.05(s) Reference to Figures or Tables

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted). Reference characters corresponding to elements recited in the detailed description and the drawings may be used in conjunction with the recitation of the same element or group of elements in the claims. See MPEP § 608.01(m).

Specification

11. The abstract of the disclosure is objected to because The abstract was not submitted on a separate sheet. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 101

12. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claims 38-44 are not isolated and purified and are therefore directed to a product of nature in light of the fact that the claimed antigens naturally occur in Helicobacter pylori in nature; the claimed invention is directed to non-statutory subject matter.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 38-46 and 49-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antigenic fragments for detection of antibodies in a biological sample and immunogenic compositions that comprise immunogenic fragments of SEQ ID NO 288 for stimulation of an immune response, does not reasonably provide enablement for make and use any composition that comprises an immunogen to serve as a vaccine (instant claim 45) that will treat or prevent Helicobacter pylori infection (see instant claim 54). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

16. The specification fails to teach how to formulate and use the claimed vaccines (instant claims 53-54 which depend from instant claims 38 and 45). The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity to Helicobacter pylori infection or disease induction. The specification teaches induction of a hyperimmune antisera immunoreactive with SEQ ID No 288 and specific epitopes contained in amino acid regions of

4-37, 40-46, 52-57, 86-109 and 104-127, 199-205, 222-229, 236-244, 250-267, 269-282 and 27-197 of SEQ ID NO:288

The specification fails to teach how to formulate and use the claimed vaccines. The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity to infection or disease induction. The specification teaches that the claimed antigens are recognized by antisera containing antibodies.

The specification does not provide substantive evidence that the claimed fragment vaccines or antigens that comprise an amino acid sequence selected from SEQ ID NO 288 of any size or sequence are capable of inducing protective immunity. This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose of preventing infections. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced. The art recognized standard for the determination of Helicobacter pylori infection is endoscopy and evaluation of tissue samples for the presence or absence of Helicobacter (see Buck et al, 1986). Data obtained from challenge experiments must demonstrate an art recognized standard of improvement over the control in order for the composition to be considered as being useful for treatment or prevention of infection and disease. This information is essential for the skilled artisan to be able to use the claimed composition (vaccines) for their intended purpose of a *Helicobacter* vaccine. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced.

The prior art teaches that Helicobacter pylori vaccines are unpredictable, specifically, in the type of effect they will have on preventing or treating infection; the ability to reasonably predict the capacity of a single bacterial immunogen, to induce protective immunity is problematic. In HP WORLD-WIDE, a publication from Brocades Pharma BV Leiderdorp, The Netherlands, February 1992, data was presented stating that immunization does not appear promising. Parenteral immunization of specific pathogen free mice with *H. felis* gave no protection against gastric colonization; previous oral infection only delayed colonization (Heap,K, Australia). The article also taught that "although intra-peyers patch immunization of killed *H. pylori* in rats shows that the gut mucosa can mount a vigorous immune response, oral immunization with either live or killed bacteria induced no significant serum or salival antibody response (Dunkley, M, Australia). Blaser (HP World-WIDE) also warned that because of the possible autoimmune component of the disease the wrong vaccine could actually make things worse."

Vaccines convey protection from infection and disease and Rappuoli et al (European Journal of Gastroenterology and Hepatology, 1993, Vol.5, (suppl. 2) pages 576-578) teach that development of a vaccine against *Helicobacter pylori* would involve four major steps:

1) identification of the factors required for virulence;

2) large-scale production and characterization of the virulence factors;

3) development of appropriate animal models to test the virulence and immunogenicity of the molecules identified; and

4) identification of the type of immunity able to prevent infection and disease.

The ability to reasonably predict the capacity of a single bacterial immunogen to induce protective immunity from in vitro antibody reactivity studies is problematic. Ellis exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of the at protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies"(page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity. See Boslego et al. wherein a single gonococcal pillin protein fails to elicit protective immunity even though a high level of serum antibody response is induced (page 212, bottom of column 2). Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy.

17. Further, the specification fails to teach the identity of the amino acid sequence fragments of any size and taken from any location that would have the claimed characteristics, i e. capable of inducing protective immunity (instant claims 45-54 Pharmaceutical composition) and to provide an adequate written description of polypeptides that share a homology with any sequence of at least 6, 8, 12, 20 amino acids (instant claims 41-43) or comprise an amino acid fragment from the SEQ Id NO 288 polypeptide that will serve as a vaccine immunogen against Helicobacter or Helicobacter pylori infection. The skilled artisan would be required to de novo locate, identify and characterize the claimed other proteins. This would require undue experimentation given the fact that the specification is completely lacking in teachings as to what polypeptides that comprise an amino acid fragment would be immunogenic and protective with the claimed characteristics of being able to prevent and treat infection.

18. The specification does not provide substantive evidence that the claimed vaccines are capable of inducing protective immunity. This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose of preventing Helicobacter pylori infections. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

20. Claims 38-39, 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Ludevid et al (US Pat. 7297847). Ludevid et al disclose the instantly claimed invention directed to fragments of SEQ ID NO 288, wherein the fragments comprise an amino acid sequence of SEQ Id NO 288, specifically amino acids 98-113 and amino acids 97-114 (Ludevid et al, SEQ ID NO

17 and 19, respectively), the fragments share 100% identity over 16 and 18 amino acids, respectively, and therefore comprise at least 6, 8 and 10 consecutive amino acids of SEQ ID No 288. Ludevid et al anticipates the instantly claimed invention as now claimed

21. Claims 38-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Tomb et al (1997, reference of cited on US PTO 1449 and International Search Report).

22. Tomb et al disclose an isolated protein antigen of Helicobacter pylori that shares 100% identity to SEQ ID NO 288 and is known as HP1341. This antigen is not described as being a hyperimmune serum reactive antigen, but the chemical structure of HP1341, described as a siderophore-mediated iron transport protein which evidences 100% identity Applicant's SEQ ID NO 288, was isolated from Helicobacter pylori strain 26695, the same strain used by Applicant, and would therefore inherently have the same or equivalent biological characteristics based upon the antigen having the identical biochemical structure.

23. Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

24. Claims 38-46, 49, 53-54 are rejected under 35 U.S.C. 102(b) as being anticipated by WO2002/66501, Legrain et al.

WO2002/66501 disclose an isolated protein antigen of Helicobacter pylori that shares 100% identity to an amino acid sequence that comprises amino acids 199-205, 222-229, 236-244, 250-267 of SEQ ID NO:288, which is a receptor binding fragment of HP1341 (see claim 6, page 477, WO 501's SEQ ID No 3186) which shares 100% sequence identity over 119 amino acids with SEQ ID No 288.

This polypeptide antigen is formulated into a pharmaceutical composition (see page 32, lines 24-28, and page 31, lines 20-242) together with an immunostimulatory adjuvant (see page 31, lines 4-8 "any pharmaceutically acceptable carrier or adjuvant can be used in the pharmaceutical composition"; page 32, line 27 and page 60, line 3 and lines 25-26 "complexes conjugated to keyhole limpet hemocyanin").

This antigen is not described as being a hyperimmune serum reactive antigen, but the chemical structure of the antigen/immunogenic polypeptide comprises amino acids 150 to 268 of HP1341, with 100% identity to Applicant's SEQ ID NO 288 over 119 consecutive amino acids. Therefore the antigen of Legrain et al would inherently have the same or equivalent biological characteristics based upon having the identical biochemical structure of the instantly claimed fragments.

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition

patentably new to the discoverer. AThe Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art. There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004). "[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); Abbott Labs v. Geneva Pharms., Inc., 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed.Cir.1999).

25. Claims 38-46, 49-50, 53-54 are rejected under 35 U.S.C. 102(b) as being anticipated by WO98/43478, Kleanthous et al.

Instant claims 38-40 WO98/43478, Kleanthous et al disclose an isolated protein antigen of Helicobacter pylori that is immunoreactive with a monospecific hyperimmune antiserum (see page 60, line 10), the antigen sharing 100% identity to an amino acid sequence of instant SEQ ID NO:288, over the 285 amino acids of SEQ ID No 288 (see Kleanthous sequence SEQ ID NO 228, referred to as GHPO894; see page 16, lines 10-11; claim 8, pages 413-415). Additional embodiments are disclosed that include polypeptide antigens without a signal sequence and fragments thereof (see page 36, lines 23-24), as well as an Helicobacter pylori antigen which shares 100% identity over 154 amino acids of instant SEQ ID NO 288 (see Kleanthous sequence SEQ ID NO 118,), which is a fragment antigen of instant SEQ ID NO 288.

(**Instant claims 40-43**)The fragments of the antigens of Kleanthous et al include amino acid sequences of at least 12, at least 20, at least 50, at least 75, and at least 100 amino acids of the

disclosed Helicobacter pylori polypeptide antigens for the purpose of maintaining antigenicity (see page 42, lines 24-25 and page 43, lines 1-2).

(**Instant claims 44-46, 49-50, 53-54**) Pharmaceutical compositions comprising the polypeptide antigens also formulated into vaccines (see page 43, lines 10-11 and lines 16-27) together with an adjuvant (see page 44, lines 24-26 "fused to a polypeptide having adjuvant activity"), and may be in administered together with a cytokine, IL-2 and IL-12 adjuvant (immunostimulatory adjuvants to enhance the immune response, see page 53, lines 3-6 and page 50, lines 5-19), or Freund's complete or incomplete adjuvant (see page 83, lines 20-25) or aluminum hydroxide (aluminum adjuvants, see page 63 and 70).

Kleanthous et al anticipates the instantly claimed invention as now claimed. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Claim Rejections - 35 USC § 103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

27. Claims 50 (additional species), 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kleanthous et al, as applied to claims 38-46, 49-50 (2 species), 53-54, in view of WO02/059148.

28. See discussion of Kleanthous et al above. Kleanthous et al teach and show the formulation of compositions that comprise Helicobacter pylori immunogenic antigens with an immunostimulatory substance(s), the immunostimulatory substances including Freund's complete or incomplete adjuvant, but differs from the instantly claimed invention by failing to show the immunostimulatory substance/adjuvant(s) to include a polycationic polymer, an immunostimulatory deoxynucleotide (ODN), a peptide containing at least two LYsLeuLys motifs, a neuroactive compound, or alum.

29. WO02/059148 teach immunostimulatory substances (see page 12, lines 1-6, paragraphs 1-5) including Freund's complete or incomplete adjuvant as taught by Kleanthous et al , as well as polycationic polymer, an immunostimulatory deoxynucleotide (ODN) (see page 14, paragraph 1) , a peptide containing at least two LYsLeuLys motifs (see page 13, paragraph 4), a neuroactive compound, and alum (see page 12, lines 1-6) in an analogous art for the purpose of formulating compositions that comprise adjuvant(s) and bacterial antigen (see page 9, line 1, lines 8-9 and paragraph 4) for stimulation of hyperimmue serum (see WO02'page 14, paragraph 4, second half of paragraph).

30. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to substitute the adjuvant(s) of WO02/059148 for the adjuvant(s) of Kleanthous et al because WO02/059148 teach and show immunostimulatory substances that are readily produced chemically, synthetically, recombinantly or derived from natural sources (see

WO02'page 12, paragraph 3; page 13, paragraph 4), and serve to activate or down regulate the adaptive immune system mediated by dendritic cells and antigen presenting cells (see page 13, lines 1-3) to insure stimulation of the desired hyperimmune serum response (see page 14, paragraph 4, second half of paragraph).

31. In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining compositions that comprise adjuvant(s) to include a polycationic polymer, an immunostimulatory deoxynucleotide (ODN), a peptide containing at least two LYsLeuLys motifs, a neuroactive compound, or alum as the immunostimulatory substance because WO02/059148 teach these immunostimulatory substances to function as adjuvants (see WO02' page 12, paragraph 2 "WO97/30721 and WO00/38528; page 13 paragraph 4, PCT/EP01/12041; page 14, paragraphs 1 and 2 WO01/93905 and WO01/24822) for enhancing the stimulated immune response resulting in the desired hyperimmune serum (see WO02', page 14, paragraph 4, second half of paragraph).

32. Kleanthous et al in view of WO02/059148 obviate the instantly claimed invention as now claimed.

Conclusion

33. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

34. Wang et al (PG-Pub 20040029129 (aka WO2002/77183) SEQ ID NO 58972 shares 100% identity over 265 amino acids of instant SEQ ID NO 288, (see page 11, claim 11, line 16; see page 136, lines 35-38 "fragments"; see page 137 pharmaceutically acceptable carrier, lines 34-38; [PG-Pub'129 [1467 "carrier"/adjuvant], see SEQ ID NO 58972 of Wang et al.)

35. PG Pub 20040009477 [0012] and Table is cited to show HP1341 siderophone mediated iron transport protein (tonB) .

36. PG-Pub 20040142413 is cited to show Helicobacter pylori to comprise about 10% gene encoding transport proteins [0036 and 0037 "TonB-ExbB-ExbD"].
37. PG-Pub 20030082211 teach TonB as a carrier outer membrane protein (see [0025-0026, 0048 "Helicobacter pylori"], and Tables 1 and 2.
38. PG Pub 20070269537 is cited to show Helicobacter iron sideorphones (see [0026, 0040, 0061, 0063, 0068, 0095, claim 2).
39. Pg-Pub 20060093594 is cited to show the administration of bovine lactoferrin to treat Helicobacter infection (see [0021 and 0068].
40. Velayudhan et al (2000) is cited to show tonB mutants; tonB encoding HP1341, the instantly elected species of invention.
41. Worst et al (1999) is cited to show TonB (also know as HP1341) is required for iron transport in Helicobacter pylori .
42. Dhaemens et al (1999) is cited to show iron regulated outer membrane proteins of Helicobacter
43. Husson et al (1993) are cited to show iron regulated envelope proteins of Helicobacter pylori.
44. WO92/19248 is cited to show a fragment of instant SEQ ID NO 288 that shares 18 consecutive amino acids from position 97 to position 114 of SEQ ID NO instant 288, and is a fragment that comprises an amino acid sequence of SEQ ID NO 288 that is only 31 amino acids in length.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/
Examiner, Art Unit 1645
March 8, 2008

/Mark Navarro/
Primary Examiner, Art Unit 1645